OBJECTIVES: To define the term 'usually' in order to ascertain potential pitfalls in its translation in any future target language. **METHODS:** This posed a particular issue in translation of the ADSC (Activities of Daily Living Inventory) in which the term appears 28 times in the form of either 'usual' or 'usually'. Discussion with the client confirmed the desired and contextual meaning of the term for this instrument, with additional guidance from clinicians, and the issue was discussed extensively with linguists for all 31 languages in this particular study. **RESULTS:** After in-depth discussion between ICON Language Services and the client, it was agreed that a more specific definition of 'usually' should be checked and applied to the translations so as to avoid risk in incorrect data collection and potentially causing offence to the target population. Concern was raised that the term could be mistaken for 'normally', which could lead to specifying what is 'normal' vs 'abnormal', i.e. making a judgement about the behaviour of the subject. We ensured that the term 'usually' was not translated as 'normally', did not imply 'normal' vs 'abnormal' behaviour and rendered the concept of frequency present in the source term 'usual'. **CONCLUSIONS:** In this project, it was vital that the term 'usually' should carry a wholly descriptive value, meaning that the phenomenon in question occurs with high frequency or by habit/custom. This should not be confused with the concept 'normally', which can carry a prescriptive connotation implying an underlying rule/order. To avoid any ambiguous or incorrect translation of the word 'usually', it is strongly advised that this be clearly defined from the start and checked throughout the linguistic validation process. Discussion between the client and linguistic staff reveals the importance of close collaboration in resolving terminology issues and improving data integrity through the conceptual equivalence of translations.

PRM195

MIGRATION OF THE FATIGUE SYMPTOMS AND IMPACTS QUESTIONNAIRE–RELAPSING MULTIPLE SCLEROSIS (FSIQ-RMS™) FROM PAPER TO AN ELECTRONIC DIARY FORMAT

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OBJECTIVES: The FSIQ-RMS™ is the first patient-reported outcome (PRO) measure of fatigue in RMS developed according to the 2009 FDA PRO guidance.1 A qualitative study was conducted to provide evidence of adequacy after adapting the FSIQ-RMS™ from paper to an electronic handheld device (eDiary). **METHODS:** Migration of the FSIQ-RMS™ to a BLU Life Play® Android™ smartphone involved modifying the instructions and landscape formatting with one item per screen. The FSIQ-RMS™ was administered to adult RMS patients at 2 US sites in a cross-sectional study. After training on the eDiary, each participant completed paper and electronic versions of the FSIQ-RMS™ in randomized order, then a device-usability questionnaire followed by one-on-one semi-structured cognitive interviews to assess comprehension of the FSIQ-RMS™, comparison between paper and electronic platforms, and usability of the eDiary. **RESULTS:** The migration study included 10 RMS patients (mean age 42 [range 27–54] years; 70% female), 8 with relapsing-remitting MS and 2 with relapsing secondary-progressive MS; mean±SD Expanded Disability Status Scale score 3.2±1.9. All participants understood and were able to view the FSIQ-RMS™ instructions, questions and response options, were able to answer the questions, and reported that the eDiary was easy to use. Based on participant comments, examples were added to one item to clarify the intended meaning. Discrepancies in response between formats were found, but most were not attributed to the device. Many participants (7/10, 70%) spontaneously reported preferring the eDiary to the paper format. Three participants suggested increasing the touch-sensitivity of the "Next" button; 5 suggested that they would have preferred a larger device (n=3) and/or font size (n=4). **CONCLUSIONS:** Results confirmed the conceptual equivalence of the FSIQ-RMS™ eDiary to the paper version and its appropriateness for use with RMS patients. Further validation of the FSIQ-RMS™ will be conducted in a Phase III RMS trial. 1Value Health 2015;18(3):A26.

PRM196

MONITORED COGNITIVE DEBRIEFING INTERVIEWS: A CASE STUDY

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OBJECTIVES: This study sought to determine the benefits to sponsor, developer, and translation provider of monitored cognitive debriefing interviews with patient questionnaires. Monitored cognitive debriefing (CD) was theorized to be particularly suitable for newly-developed questionnaires with minimal or no previous linguistic validation (LV), and for adapted questionnaires (i.e., a disease-specific instrument adapted to a new disease). **METHODS:** Thirty (30) CD interviews were carried out on a newly-developed patient instrument in six languages. Of those, sixteen (16) interviews were monitored by the sponsor. All languages were selected by the sponsor and a percentage of those interviews were monitored, the first languages to undergo LV. The translation provider recruited patients, provided interpreters, secured facilities with two-way mirrors and audio-visual recording capabilities, and performed the interviews. The monitor noted any sub-threshold issues that were outside of typical LV data capture rubric. Upon noting such issues in more than one country, the test authors would convene a meeting to consider if the PRO linguistic validation protocol or PRO source instrument required revision. **RESULTS:** The monitor suggested follow-up questions as needed during the CD interviews, tailoring the process to target specific dimensions of the PRO. Issues were tracked across languages by the monitor, and the interviewer asked subjects for their preference for alternative translations, when suggested by the monitor. Compared to those interviews which were unmonitored, on average, subjects made more comments overall, and more comments leading to a translation revision. **CONCLUSIONS:** Monitored interviews are beneficial for the validation of newly-developed or adapted instruments. This augmentation to CD provides a means of vendor management and early identification of issues during LV that are outside of the typical data capture rubric. The process enables the sponsor to suggest follow-up questions or modifications on-site, thus correcting issues preemptively that may negatively impact understanding and subsequent data pooling.

PRM197

DEVELOPMENT OF A MEASURE TO ASSESS SEVERITY OF MPS II: THE DISEASE SEVERITY SCORE

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OBJECTIVES: To date, no mucopolysaccharidosis type II (MPS II) measure capturing disease severity exists other than classifying patients with and without cognitive impairment. This study aimed to develop a clinician-reported outcome (ClinRO) to assess somatic and central nervous system (CNS) severity in patients with MPS II. **METHODS:** Following a literature review to identify key indicators of MPS II severity and interviews with pediatric specialists, two interactive video conferences with clinicians from the Hunter Outcome Survey (HOS) working groups were conducted to review the draft instrument and discuss definitions and descriptions of observable signs and symptoms and objective clinical parameters. Patient vignettes based on hypothetical cases with different ranges of severity were developed to evaluate inter-and intra-rater reliability. Further refinement of items and descriptions were discussed in additional expert panels to obtain consensus on content validity, including wording and importance of individual items. **RESULTS:** The current version of the Disease Severity Score (DSS) comprises two components, somatic and CNS, with 17 items covering 11 domains altogether. The somatic component (11 items) includes respiratory, hearing, cardiac, neurology, and orthopaedic domains. The CNS component (6 items) covers cognition, language & communication, activity level & focus, toileting, sleeping disorder, and seizures. Most items used a severity rating (normal, mild, moderate, and severe) accompanied by a clinical description; some items in the Somatic component also contain objective clinical parameters. Intra-rater reliability was demonstrated for all items (κappa>0.80). **CONCLUSIONS:** A novel and innovative approach was used in the development of this ClinRO with the consensus of experts in MPS II. The DSS is intended to assess disease severity using observable signs and symptoms, track somatic and CNS disease severity and progression over time and to compare severity of MPS II across centers internationally. A scoring algorithm and assessments of validity and responsiveness are currently being developed.

PRM198

COST ANALYSIS STUDY OF ORAL ANTI-DIABETIC DRUGS AVAILABLE IN INDIAN GOVT GENERIC (JAN AUSHADHI,JEEVANDHARA) DRUGS AND BRAND DRUGS MARKET IN RURAL / URBAN AREA OF GUNTUR, ANDHRAPRADESH, INDIA

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OBJECTIVES: To analyze the cost variation of oral anti-diabetics of different generic drugs sold at Jan Avushadhi and jeevanadhara and Retail pharmacy available brand names of single compound and combination compounds to evaluate the difference in cost , percentage variation of cost. **METHODS:** Cost of single and combination compound drugs manufactured by different companies, in the same strength, number and dosage form was obtained from Current Index of Medical Specialties" July-October 2014 and jan avushdhi,jeevandharaa drugs were compared upto February -2015. **RESULTS:** In Single compound drug usage, among sulfonylurea group of drugs, Glibenclamide (2 mg) shows maximum price variation of 1980%, while Glipizide (10mg) shows variation of 55.61%. In Biguanides & Thizolidinediones groups Of drugs Metformin (1000 mg) show Maximum price variation is 125.37%, Metformin (500 mg) leat variation is 30 % and Piglitazone (30mg) show Maxmum variation 3060.97% and least variation Pioglitazoe (15 mg) is 3275 respectively. . In α-glucosidases inhibitor group of drugs,Miglitol shows maximum price variation of 135.50 % and Minimum variation is 41.93 %. Meglitinides group of drugs. In this group, Rapaglinide (0.5 mg) shows Maximum price variation of 79.25 % and Minimum variation is 60 % respectively. Dipeptidyl peptidase IV inhibitors (e.g., Sitagliptin), group Sitagliptin (100 mg) shows Maximum price variation of 902.3 %. In combination therapiesGlibenclamide + Metformin (5 mg+ 500 mg) combination shows the maximum variation up to 2400 % and Glipizide + Metformin (2.5mg + 250mg) showed minimum price variation of 28.60% respectively. **CONCLUSIONS:** Study has concluded that the cost variation increases when competition between the manufacturing companies and generic companies. cost which company providing less cost and whether these drugs are available janavushadhi or jeevandhara or generic pharmacy shops. So that we can minimize the cost burden on consumers.

PRM199

MEASUREMENT INVARIANCE OF THE WHOQOL-OLD MODULE ACROSS DIFFERENT DEMOGRAPHIC GROUPS IN TAIWAN'S ELDERLY PEOPLE

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OBJECTIVES: The purpose of this study is to examine the measurement invariance of the WHOQOL-OLD Module across different demographic groups in Taiwan's elderly people. By testing the differential item functioning (DIF), the presence of DIF indicates measurement variance. In other words, item score of measurement scale is dependent on some irrelevant characteristics. If this condition is observed the interpretation of items would be confounded. **METHODS:** A total sample 524 participants involved in this study, but only 503 participants (96%) completed the whole questionnaire. The questionnaire included the WHOQOL-OLD and the demographic characteristics (age, gender, and education). Multiple-indicator multiple-cause latent variable (MIMIC) model was used to explore the relationship between the latent factors and demographic variables. Data was analyzed by using the Mplus7.0 and SAS9.4 software. **RESULTS:** Multiple-indicator multiple-cause latent variable model showed significant differences were observed on sensory abilities, death and dying for different age and education and on social participation only for different education. However, the significant differences can be eliminated when adjusting for DIF on item1 and item18, respectively, on sensory abilities and social participation. **CONCLUSIONS:** The result implies that age and education should be controlled when comparing sensory abilities, death and dying and social participation facets.